IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: WAVE 8 CASES ON ATTACHED EXHIBIT A	

PLAINTIFFS' MOTION TO EXCLUDE
CERTAIN OPINIONS OF DR. EDWARD STANFORD

Pursuant to Federal Rules of Evidence 702, 403, and 104, Plaintiffs respectfully request that the Court exclude certain opinions and testimony of Defendants' expert, Edward Stanford, M.D. In support of their Motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Stanford seeks to offer testimony that is not helpful for the jury, clearly exceeds the bounds of his qualifications, and is founded on insufficient facts and unreliable methodology.[1] Dr. Stanford has been a hospital administrator for nearly the past four years and essentially stopped practicing medicine full time in 2015. (Exhibit B, Deposition of Edward Stanford, page 13, 21). Dr. Stanford describes this as his "administrative retirement." *Id.* He has not performed any surgery, much less any surgery SUI surgery, in almost four years. *Id.* Despite being in "administrative retirement," Dr. Stanford offers opinions on the current state of mind of physicians across the country, opinions that contradict his own sworn testimony from a prior

[1] *See Phelan v. Synthes*, 35 Fed. Appx. 102, 105 (4th Cir. 2002) (the reasoning or methodology underlying testimony must be scientifically valid and able to be properly applied to the facts in issue.).

deposition, opinions as to current standard of care in a field he no longer practices in[2], and at times seemingly is just making things up as he goes.

Dr. Stanford offers opinions on five separate sling mesh devices in his 20 page report. Specifically, this Court should exclude Dr. Stanford's opinions regarding: (1) the adequacy of Defendants' product warnings and IFUs, including opinions regarding what risks of the devices other doctors know of; (2) any opinion regarding safety, efficacy, or personal satisfaction rates of the mesh products observed in her own practice; and (3) whether the polypropylene mesh degrades inside the human body.

LEGAL STANDARD

Under Rule 702 of the Federal Rules of Evidence, as interpreted by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), an expert witness may be qualified by "knowledge, skill, experience, training or education." Fed. R. Evid. 702. The witness's testimony also must represent "scientific knowledge," meaning that it is supported by appropriate validation; and it must assist the jury, meaning that it must be relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). Expert testimony is admissible if the expert is proven to be qualified and said testimony (1) "will help the trier of fact to understand the evidence or to determine a fact in issue," (2) is "based upon sufficient facts or data," (3) is "the product of reliable principles and methods" and (4) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. Opinion evidence may be admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. In the end, an expert's testimony is admissible if it

[2] For example, Dr. Stanford writes, "This has resulted in MUS becoming the operation of choice in Europe, Asia, South America, South Africa, Australasia and North America for treatment of SUI with several million procedures performed worldwide." He provides no support for this inaccurate personal guess of his.

"rests on a reliable foundation and is relevant." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

The duty rests with Dr. Stanford to proffer expert testimony and "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Even if the expert is qualified and her testimony is reliable, "testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig*., 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15,2014) *reconsideration denied*, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). In other words, his testimony must "fit" the case, and there must be a "valid scientific connection to the pertinent inquiry as a precondition to admissibility. *Id*.

ARGUMENT

1. Dr. Stanford opinions on the adequacy of defendants' warnings and what other doctors know about the risks of pelvic mesh devices should be precluded pursuant to *Daubert*

Dr. Stanford's testimony is unreliable as his opinions on the adequacy of defendants' warnings are based on nothing more than personal convictions regarding what risks are commonly known to physicians about the device and not based on any industry standards or regulations governing the adequacy of warnings. Thus, they are thus *ipxe dixit* and precluded under *Daubert*. Moreover, Dr. Stanford not only guesses as to the knowledge and state of mind of every pelvic floor surgeon but he also guesses as to the state of mind of every potential patient considering a surgery to correct SUI. He says any changes to the warnings information supplied by defendants "most likely would not have changed the decision by the patient to receive the implant" and surgeons don't read the device instructions for how to properly implant the device

but even if they did it "would not change the surgeon's decision." (Exhibit C, Report, page 18-20 and 6). He concludes, without any support, it is a "double standard" that the "TVT be required to have an unrealistically robust or complete IFU..." *Id.* at page 20. Apparently, Dr. Stanford in his "administrative retirement" is aware that defendants did change their warnings to make them complete and realistically robust in 2015 after he entered in his "administrative retirement." Dr. Stanford does not reference any independent knowledge of FDA requirements or knowledge of industry standards governing the adequacy of warnings and instructions for use in his report. Finally, in contradiction of what he writes in his report dated September 28, 2018 about physicians not reading the instructions or relying on important safety information from defendants, Dr. Stanford actually testified in 2017 that when he practiced medicine he read the instructions and even memorized them. Ex. B at pages 45, 75 77. He testified not only, "as a surgeon" did he read and memorize the TVT IFU, but this was his common practice "as a surgeon" to "familiarize" himself with the instructions for use and other company materials, like Ethicon's Surgeon Monograph *Id.* In fact, Dr. Stanford testified he relied on training provided by Ethicon when he traveled to Sweden and spent five days with the inventor of the TVT device "to learn about this procedure." *Id* at page 18, 65. Because his opinions have no support, are unreliable and contradict his prior testimony under oath they don't meet Daubert. Such opinions lie at the heart of what *Daubert* and its progeny have found inadmissible.

This Court is obliged to exercise a "gatekeeping" function to ensure that expert testimony is both relevant and reliable. FED. R. EVID. 702; *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999) (*citing Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993)). This obligation applies to all types of expert testimony, not merely scientific analysis. *Kumho Tire*, 526 U.S. at 149; *Holsesapple v. Barrett*, No. 00-1537, 2001 WL 208490, at *1 (4th Cir. 2001).

The proponent of the testimony has the burden of proving both relevance and reliability. *Bickel v. Pfizer, Inc.*, 431 F. Supp. 2d, 918, 921 (N.D. Ind. 2006). While an expert who is a urologist or pelvic floor surgeon may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU. *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015). Dr. Stanford does not possess the additional expertise to offer expert testimony about what an IFU should or should not include or the adequacy of these materials, his testimony regarding these issues should be excluded.

Also troubling, is Dr. Stanford disregard for scientific literature that is contrary to his guessing that all physicians know all risks all the time. For example, the seminal article by Abbot et al,[3] discussing the concern physicians are not aware of the risks associated with mesh due to fact mesh complications are treated by highly specialized doctors at research hospitals is not included on his reliance list or even referenced in his report.

Federal courts have consistently held that *ipse dixit* – opinions justified solely by the fact that the expert holds them -- are inadmissible. *See, e.g., GE v. Joiner*, 522 U.S. 136, 146 (1997); *see also Pampered Chef v. Alexanian*, 804 F. Supp. 2d 765, 794 (N.D. Ill. 2011) ("If admissibility could be established merely by the *ipse dixit* of an admittedly qualified expert, the reliability prong would be, for all practical purposes, subsumed by the qualification prong.") The Fourth Circuit concurs. *Holesapple*, 2001 WL 208490 at *2 ("[I]t still is a requirement that the expert opinion evidence be connected to existing data by something more than the 'it is so

[3]Exhibit D "concern that physicians who perform these mesh procedures may not be aware of the complications their patients experience..."

because I say it is so' of the expert."). This Court has also excluded *ipse dixit* opinions. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 603 (S.D.W. Va. 2013).

As this Court held in *Sanchez*: "[a]n expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead 'selectively [chooses] his support from the scientific landscape.' '[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable.'" [4]

II. Dr. Stanford's guesses about his personal experience related to the safety and efficacy of the TVT should be excluded because they are not based on any objective standard, and his analysis and methodology are flawed

Dr. Stanfrod should be precluded from testifying about her perceived safety, efficacy, and patient satisfactions rates with the subject products from his practice, as those opinions are entirely unsupported by any reliable methodology, nor have they been subject to peer review. This court has already ruled that an expert cannot relate precise statistics based on their own assurances that those statistics are reliable. *In re Ethicon*, 2016 WL 4542054 (S.D. W. Va. 2016).

Dr. Stanford carefully takes vague and general stabs at guessing his safety data with the TVT. He makes claims that are impossible to verify, including, "In my hands, I cannot recall a bladder or urethral injury in several years." Ex. B at page 9. Dr. Stanford has not published any data on his success or catastrophic TVT failures nor did he keep a patient registry. Being that he has been in administrative retirement that past few years it is clear any statement where he guesses how his patients are performing doesn't meet Daubert standards.

[4] *Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 U.S. Dist. LEXIS 137189, *70 (S.D. W. Va. Sept. 29, 2014) (citations omitted).

III. Dr. Stanford's opinion related to mesh degradation is completely unsupported, and therefore, unreliable

Dr. Stanford devotes a half page in his report to the topic of mesh degradation. Ex B at page 15. He states he isn't aware of a single article that discuss mesh degradation. *Id.* The only article he is apparently aware of is one written by an expert witness hired by defendants who not shockingly concludes mesh degradation is a "myth." Dr. Stanford didn't review the seminal internal documents on this subject that have now been used at multiple trials, including Ethicon's own studies that conclude polypropylene does degrade. He says some not only unreliable things about mesh degradation, but makes statements that are strange and have no place in an expert report. He even compares mesh implanted in a woman's vagina to a steal beam, "I offer a clinical analogy. One can see that the surface of the steel beam of a bridge degrades over time however the strength of the scaffold is largely preserved and generally considered safe." *Id.* Clearly this is not a man who is an expert in this area and his opinions should be excluded. He failed to consider contrary scientific literature on the subject and has no basis or methodology, much less a reliable one, for much of what of what he makes up about mesh degradation and steal beams on bridges.

CONCLUSION

Ethicon, as the proponent of the expert testimony, bears the substantial burden of establishing that Dr. Stanford is sufficiently qualified and that the proposed testimony satisfies the applicable evidentiary standards for the admission of expert testimony. Considering the lack of knowledge, and reliability inherent in the opinions discussed above, Ethicon cannot carry this burden and his testimony should be accordingly limited.

Dated: December 18, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 18, 2018, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

s/ Thomas P. Cartmell